**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

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| **IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL 2327** |
| **THIS DOCUMENT RELATES TO ALL CASES** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**DEFENDANTS JOHNSON & JOHNSON AND ETHICON, INC.'S REPLY IN SUPPORT OF MOTION FOR ORDER REGULATING PLAINTIFFS' COUNSEL'S *EX PARTE* CONTACTS WITH TREATING PHYSICIANS**

## I. INTRODUCTION.

Plaintiffs do not dispute that their counsel have been engaging in wide-ranging *ex parte* contacts with treating physicians about issues that have nothing to do with the treatment of their clients. They admit it. Plaintiffs admit that their counsel's *ex parte* contacts as described by Defendants are part of the "established practice" in this MDL. *See* Pls.' Opp'n at 4. As a consequence, Plaintiffs' counsel have now met with "hundreds" of physicians for "a few hours" at a time before their fact depositions to pore over snippets of cherry-picked documents that often post-date the physicians' treatment decisions; published medical articles that the physicians never considered; and the parties' litigation theories. *Id.* at 4, 6, 13, 15. And in what amounts to veiled threats to sue the physicians for malpractice, Plaintiffs' counsel warn the physicians about Defendants' purported efforts to "point the finger" at them. *See id.* at 6. Plaintiffs offer no convincing explanation for why this Court should allow their counsel's established practice—

which Magistrate Judge Stanley initially permitted based on a limited evidentiary record—to continue.

***First***, Magistrate Judge Stanley's interlocutory ruling in the *Bard* MDL is *not* the law of the case in *this* MDL. Her ruling therefore poses no obstacle to the Court's imposition of the sensible limitations that Defendants seek. And even if the law-of-the-case doctrine applied, this Court plainly has discretion to alter its course.

***Second***, there are good reasons why the Court should make that course correction now. The key assumption underlying Magistrate Judge Stanley's ruling—*i.e.*, that the treating physicians are *plaintiffs'* witnesses—is simply incorrect. In many cases, the physicians are named as *defendants*. In those case where they are not so named, the physicians are and should be *independent* fact witnesses, and they should be giving *independent* fact testimony—not testimony that is tainted by Plaintiffs' counsel's unrestrained *ex parte* contacts and the *in terrorem* specter of a medical malpractice claim. The parties in this MDL are preparing to depose up to *800 treating physicians* as part of the 200 Wave 1 cases. It is imperative that the Court set reasonable ground rules now so that Plaintiffs' counsel do not continue to reap the same unfair advantage that they obtained in the past as a result of Magistrate Judge Stanley's ruling. Numerous courts have imposed reasonable limitations where, as here, plaintiffs' counsel have engaged in an established practice of improper *ex parte* contacts. Plaintiffs offer no serious response to these well-reasoned authorities. Instead, they rely on a handful of mostly unpublished decisions that are entirely devoid of any meaningful analysis.

***Third***, Plaintiffs provide no reasoned explanation for why their counsel actually need to engage in unfettered *ex parte* contacts. Plaintiffs insist that their counsel need to discover information relevant to their failure-to-warn claims. But Plaintiffs' counsel can discover that

information at deposition—when Defendants first learn of it. The *Actos* court recently *rejected* Plaintiffs' argument that their counsel need to engage in secret *ex parte* meetings to discover information relevant to their failure-to-warn claims. This Court should do the same. Nor are the *ex parte* contacts at issue necessary to counteract Defendants' regulated interactions with treating physicians that take place *outside* of litigation and employ marketing materials already produced in discovery.

***Fourth***, by engaging in unrestrained *ex parte* contacts, Plaintiffs' counsel are not only reprogramming the memories of key fact witnesses; they are impermissibly transforming those witnesses into retained experts without complying with the expert witness disclosure requirements required by the Federal Rules of Civil Procedure. The Court should require Plaintiffs to comply with those rules.

## II. ARGUMENT.

For the reasons explained in Defendants' Motion and below, the Court should limit Plaintiffs' counsel's *ex parte* contacts with treating physicians as requested.

### A. Magistrate Judge Stanley's Ruling In The *Bard* MDL Is Not The Law Of The Case In *This* MDL.

Plaintiffs assert that Magistrate Judge Stanley's ruling in the *Bard* MDL is the law of *this* case. *See* Pls.' Opp'n at 3 ("Judge Stanley's ruling has been the law of the case in these MDLs for more than three years . . . ."). It plainly is not.

As the Fourth Circuit has explained, the law-of-the-case doctrine is limited in its scope: "'when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages *in the same case*.'" *Columbus-Am. Discovery Grp. v. Atl. Mut. Ins. Co.*, 203 F.3d 291, 304 (4th Cir. 2000) (quoting *Arizona v. California*, 460 U.S. 605, 618 (1983)) (emphasis added). The doctrine does *not* apply to defendants in a subsequent suit who were not

parties to the first suit. *See Winchester Homes, Inc. v. Osmose Wood Preserving, Inc.*, 37 F.3d 1053, 1059 (4th Cir. 1994) (where defendants were not parties in prior case, "there is no collateral estoppel effect as to facts, issues, or claims decided in" earlier case and law-of-the-case doctrine does not apply); *see also In re Microsoft Corp. Antitrust Litig.*, 355 F.3d 322, 328 (4th Cir. 2004) (law-of-the-case doctrine applies "where the parties were the same, the issues were the same, the facts were the same, and even the court was the same"). And even when the requirements for the doctrine to apply are met, the "instruction to adhere to earlier decisions of law in a case" is entirely *discretionary*. *Columbus-Am.*, 203 F.3d at 304; *see also id.* (noting circumstances in which appellate court decisions establishing law of the case might not be followed).

Because Defendants are not parties to the *Bard* MDL and had no opportunity to brief or argue the *ex parte* contacts issue that arose in that proceeding, Magistrate Judge Stanley's ruling is not the law of the case in *this* MDL. Plaintiffs cite *no* contrary authority. In short, Magistrate Judge Stanley's ruling does not bind Defendants. *See, e.g.*, *Winchester Homes*, 37 F.3d at 1059.

Moreover, the fact that Magistrate Judge Eifert declined in 2014 to revisit that ruling (*see* Pls.' Opp'n at 2-3) does not make it the law of this MDL. Counsel for Bard had asked Magistrate Judge Eifert for an opportunity to submit briefing on the *ex parte* contacts issue in light of the Court's pretrial order establishing that treating physicians in the *Bard* MDL would be deposed through written questions. *See id.*, Ex. 3 (Transcript of August 15, 2014 Status Conference Before Magistrate Judge Eifert in *Bard* MDL) at 28-29. Magistrate Judge Eifert declined to allow that briefing in part because she viewed Magistrate Judge Stanley's ruling as the law of the case in the *Bard* MDL (*see id.*, Ex. 3 at 35) and in part because the plaintiffs argued that the Court was in the process of evaluating the procedures for deposing treating

physicians in that proceeding. *See id.*, Ex. 3 at 36 ("This is in the hands of Judge Goodwin right now."). The fact that the Court was re-evaluating those procedures demonstrates that Magistrate Judge Stanley's ruling—which she issued based on a limited evidentiary record—is an interlocutory discovery order subject to review and revision. Plaintiffs' reliance on Magistrate Judge Eifert's decision not to revisit that ruling is thus ill-founded.

### B. There Are Numerous Reasons Why The Court Should Decline To Follow Magistrate Judge Stanley's Ruling.

Even if the law-of-the case doctrine applied—and it does *not*—the Court should exercise its discretion to not follow Magistrate Judge Stanley's ruling. *See Columbus-Am.*, 203 F.3d at 304.

#### 1. Magistrate Judge Stanley wrongly assumed that treating physicians are plaintiffs' witnesses.

A key assumption underlying Magistrate Judge Stanley's ruling is that "attorneys are expected to prepare *their witnesses* for the rigors of giving testimony." Defs.' Mot. at 16 (quoting Pretrial Order # 48) (emphasis added). As Defendants explained, however, the treating physicians are not *Plaintiffs'* witnesses. Instead, they are and should be *independent* fact witnesses who have *no* obligation to support the litigation interests of any party to this lawsuit. *See id.* at 16 (citing cases).

Plaintiffs do not dispute this fundamental proposition. Instead, they merely echo Magistrate Judge Stanley's statement at the hearing on Bard's letter brief to the effect that plaintiffs' counsel "would be derelict if they did not interview *their* witnesses." Pls.' Opp'n at 2, 5 (emphasis added); *see also id.* at 8. Plaintiffs' reliance on that erroneous statement underpins all of their arguments. Thus, Plaintiffs argue that their counsel "not only have the *right*, but an *obligation* to inquire about *their* doctors' knowledge, training, experience and technique relative to these products, as well as the scope and substance of Defendants' physician training programs

and materials." *Id.* at 6-7 (emphasis added); *see also id.* at 15 ("Plaintiffs' counsel's discussions with their doctors are not only appropriate, but as Judge Stanley agreed, they are necessary.").

Plaintiffs' argument that the treating physicians are *their* witnesses is belied by the fact that numerous plaintiffs in this MDL have named physicians as medical malpractice *defendants*. No plaintiff seriously can suggest that she has a right to have her counsel interview a treating physician *ex parte* before naming that physician as a defendant. Nor is it debatable that the *in terrorem* specter of being named as a medical malpractice defendant might shape a physician's testimony at deposition. *See, e.g.*, *Polett v. Pub. Commc'ns, Inc.*, 83 A.3d 205, 220 (Pa. Super. 2013) (physician inserted "finger pointing" causation opinion in medical records after patient requested that he execute tolling agreement extending limitations period for lawsuit), *appeal granted*, 91 A.3d 1237 (Pa. 2014). In *Crews*, Dr. Norvell received an *ex parte* warning that Ethicon would "point the finger" either at him or the plaintiff. Defs.' Mot. at 3. Ultimately, Dr. Norvell testified that he might not have implanted Ethicon's Prolift device into Ms. Crews had he known the cherry-picked information that counsel shared with him *ex parte*. *See id.* at 4.

Because the treating physicians are *not* Plaintiffs' witnesses, Plaintiffs' reliance on Magistrate Judge Stanley's ruling is misguided. The physicians are either defendants or prospective defendants, or they are and should be independent fact witnesses who should be giving independent fact testimony. There is no reason why Plaintiffs' counsel need to "prepare" the physicians *ex parte* to testify on matters that fall outside the scope of the physician-patient privilege. *See* Pls.' Opp'n at 2, 5, 8, 15.

**2. Magistrate Judge Stanley's ruling is not working, and it would be unreasonable and unfair to simply maintain the status quo.**

In the *Bard* MDL, the defendant presented Magistrate Judge Stanley with limited briefing identifying a single example of improper *ex parte* contacts. On the basis of that single example,

Magistrate Judge Stanley declined to impose a limiting order. In the time since Magistrate Judge Stanley issued her ruling, however, plaintiffs' counsel in this and the other pelvic mesh MDLs pending before the Court have met with *hundreds* of physicians before their fact depositions for *hours* at a time to discuss the defendants' corporate documents and other information that the physicians never considered when making their treating decisions. *See* Defs.' Mot. at 2-6; Pls.' Opp'n at 4 n.1, 13.

Plaintiffs' counsel's established practice in this MDL involves the very behavior that courts across the country have cautioned is improper. For example, Judge Fallon's stated purpose in permitting plaintiffs' counsel in the *Vioxx* litigation to meet *ex parte* with treating physicians was to allow "plaintiff's counsel to interview the plaintiff's treating physician regarding the plaintiff's personal medical history." *In re Vioxx Prods. Liab. Litig.*, 230 F.R.D. 473, 475 (E.D. La. 2005). Judge Fallon made clear in the later hearing cited in Defendants' Motion that the purpose of allowing *ex parte* interviews was to allow plaintiffs' counsel to discuss with the physicians the "private matters" protected by the physician-patient privilege—"not to expose them or give them one-sided presentations about the other side." Defs.' Mot. at 9-10 (quoting Hr'g Tr., *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657 (E.D. La. Apr. 27, 2006)). Judge Fallon expressed concern that allowing plaintiffs' counsel to "go into other things" outside the plaintiffs' medical records "d[id] not seem reasonable." *Id.*

Several courts have expressed the same concern and have imposed reasonable limitations on the permissible scope of plaintiffs' counsel's *ex parte* contacts. *See id.* at 10-11 (citing *In re: Chantix (Varenicline) Prods. Liab. Litig.*, No.: 2:09–CV–2039–IPJ, 2011 WL 9995561, at *4 (N.D. Ala. June 30, 2011); *In re Ortho Evra Prods. Liab. Litig.*, No. 1:06-40000, 2010 WL 320064, at *2 (N.D. Ohio Jan. 20, 2010); *In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1964

RWS, 2009 WL 775442, at *2-*3 (E.D. Mo. Mar. 20, 2009); *Coordination Proceeding Special Title (Rule 2.550) Actos Prod. Liab. Cases*, No. CGC-12-519107, 2015 WL 1387938, at *8 (Cal. Super. Ct. Mar. 20, 2015); *In re Pelvic Mesh/Gynecare Litig.*, No. ATL-L-6341-10 (N.J. Super. Dec. 3, 2013), at *6). This Court should follow these well-reasoned authorities.

The fact that Plaintiffs' counsel have engaged in hundreds of *ex parte* interviews over the past few years on topics that do not fall within the scope of the physician-patient privilege is no reason to maintain the status quo. Discovery in the 200 Wave 1 cases is getting under way. The parties will depose up to *800 treating physicians* by February 1, 2016. *See* Pretrial Order No. 195, *In re: Ethicon, Inc., Pelvic Repair Syst. Prods. Liab. Litig.*, MDL No. 2327, Dkt. No. 1686, at 1-2. Plaintiffs' counsel should not have free reign to reprogram the memories of 800 physicians over the next four months. The parties in this MDL are at a crucial juncture in the proceeding. For the massive Wave 1 discovery effort to produce meaningful and informative results, the Court should impose sensible limitations on the permissible scope of Plaintiffs' counsel's *ex parte* contacts. Doing so will not prejudice Plaintiffs. It will simply help to ensure that the physicians are able to provide unbiased fact testimony. That should be the goal.

**3. Magistrate Judge Stanley's ruling runs counter to the emerging trend in the case law.**

When Magistrate Judge Stanley issued Pretrial Order # 48, she assumed that she needed statutory authority to issue a limiting order. *See* Defs.' Mot. at 15. That assumption was incorrect. Courts have inherent power to regulate *ex parte* conduct that abuses the integrity of the judicial process. *See id.* (citing cases). In fact, Defendants cited two decisions from *this* Court that support that unremarkable proposition. *See id.* Plaintiffs do not address this authority. *See* Pls.' Opp'n at 5. Instead, they simply ignore it.

Plaintiffs likewise ignore the two most recent decisions in what is an emerging trend in product liability litigations such as this one—*i.e.*, the 2015 decision in the *Actos* litigation and the 2013 decision in the New Jersey pelvic mesh litigation. *See Actos Prod. Liab. Cases*, 2015 WL 1387938; *In re Pelvic Mesh/Gynecare Litig.*, No. ATL-L-6341-10 (N.J. Super. Dec. 3, 2013). Plaintiffs acknowledge that Magistrate Judge Stanley did not have an opportunity to consider these recent decisions. *See* Pls.' Opp'n at 11. Plaintiffs' suggestion that Magistrate Judge Stanley would have rejected them had she had that opportunity (*see id.*) is pure speculation. The decisions are carefully-reasoned and lengthy.

Rather than respond to Defendants' well-reasoned authorities, Plaintiffs rely on a handful of mostly unpublished decisions that are entirely devoid of meaningful analysis. For example, Plaintiffs rely on an order in the *In re Mentor Corp. Obtape Transobturator Sling Products Liability Litigation*. *See* Pls.' Opp'n at 11. Plaintiffs say it is "inexplicable" that Defendants did not cite that order. *Id.* Yet, the *Obtape* order is not published on either Westlaw or LexisNexis. Nor does it discuss what *ex parte* contacts (if any) had occurred in the *Obtape* MDL. *See id.*, Ex. 9. Accordingly, there is no basis for concluding that the *Obtape* court was confronted by the type of improper *ex parte* contacts that repeatedly have occurred here. Thus, the *Obtape* order is not persuasive, much less precedential.

Next, Plaintiffs rely on two unpublished state court orders issued by the Philadelphia Court of Common Pleas in the *Phen-Fen* litigation. *See id.* at 8 & n.5. These unpublished orders contain even less analysis than the *Obtape* order. The first *Phen-Fen* order contains a grand total of *five* sentences that fail to elucidate why the court ruled as it did. *See id.*, Ex. 5. The one thing that appears clear from the court's murky order is that the court treated the defendants' motion not as one to limit plaintiffs' counsel's *ex parte* contacts but rather as one seeking "some form of

preclusion of the testimony." *Id.*, Ex. 5. The second *Phen-Fen* order comprises just a *single* sentence that provides no clue whatsoever about the merits of the defendants' argument or the court's reasons for denying their motion. *See id.*, Ex. 6.

When it comes to Plaintiffs' published cases, their authorities fare no better. Plaintiffs purport to rely on *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Prods. Liab. Litig.*, 2011 WL 9996459 (S.D. Ill. Mar. 4, 2011). *See id.* at 9-10. But that case is factually distinguishable. In *In re Yasmin*, the defendants' concerns about inappropriate physician contacts had not yet materialized. *See* 2011 WL 9996459 at *1 (noting that defendants "are concerned that such conduct could unfairly bias treating physicians and lead to 'woodshedding[]'" and that plaintiffs argued that defendants' concerns had not "come to fruition"). Thus, there was no urgency necessitating court intervention. Here, by contrast, Plaintiffs' counsel already have embarked unapologetically on an *ex parte* campaign to improperly influence the testimony of treating physicians. Defendants discussed multiple examples where Plaintiffs' counsel successfully tainted the physicians' testimony. *See* Defs.' Mot. at 3-5 & n.4.[1] There undoubtedly are many others, as Plaintiffs themselves suggest. *See* Pls.' Opp'n at 4 n.1, 13. Unlike in *In re Yasmin*, court intervention *is* required here.

[1] In *Crews*, for example, Plaintiffs' counsel lobbied Dr. Norvell at three *ex parte* meetings lasting four and one-half hours. *See* Defs.' Mot. at 3. Counsel warned that Ethicon might "point the finger" at the doctor; shared highlighted snippets of select Ethicon documents; provided his spin about what some "new" evidence supposedly shows about the safety of the Prolift device; and rehearsed questions that he intended to ask at the upcoming deposition and inquired as to the doctor's anticipated answers. *See id.* at 3-4. Dr. Norvell ultimately testified that he might not have implanted Ethicon's Prolift device into Ms. Crews had he known the cherry-picked information that Plaintiffs' counsel shared with him *ex parte*. *See id.* at 4. Dr. Woodruff gave similar testimony in *Flowers* after an *ex parte* meeting in which Plaintiffs' counsel showed him a medical article and multiple regulatory documents that post-dated Ms. Flowers' implant procedure. *See id.* at 4-5.

Plaintiffs also rely on *In re: Kugel Mesh Hernia Repair Patch Litig.*, MDL Docket No. 07-1842ML, 2008 WL 2420997 (D.R.I. Jan. 22, 2008). *See id.* at 8-9. But again, this case does not help Plaintiffs. At issue in *In re: Kugel Mesh* was whether defense counsel could meet *ex parte* with treating physicians. *See* 2008 WL 2420997 at *1. Here, Defendants are not seeking such relief. Instead, they merely seek an order restricting Plaintiffs' counsel's *ex parte* contacts to subjects that fall within the scope of the physician-patient privilege. Nothing in *In re: Kugel Mesh* suggests that that relief is unwarranted. On the contrary, the case actually supports Defendants' position, because the court there recognized that protecting "'the relationship between a doctor and patient'" is the very reason for "'allowing plaintiffs' counsel to engage in *ex parte* interviews with those doctors.'" *Id.* (quoting *In re Vioxx Prods. Liab. Litig.*, 230 F.R.D. at 477). In other words, *In re: Kugel Mesh* stands for the unremarkable proposition that Plaintiffs' counsel may meet *ex parte* with treating physicians to discuss matters that fall within the scope of the physician-patient privilege. Defendants do not disagree. Their point—which *In re: Kugel Mesh* does not dispute—is that the privilege cannot justify a plaintiff's counsel's effort to campaign *ex parte* in favor of his client's litigation theories—*i.e.*, because those theories fall well *outside* the permissible scope of the privilege. *See* Defs.' Mot. at 9-12.

In short, the approach adopted in Pretrial Order # 48 runs counter to the considered decisions of numerous courts that have seen fit to impose sensible limitations on the permissible scope of plaintiffs' counsel's *ex parte* contacts. Plaintiffs offer no meaningful response to these authorities. And the authority on which they do rely is either inapposite or devoid of analysis.

### C. Plaintiffs Fail To Explain Why Their Counsel Need To Engage In Unrestrained *Ex Parte* Contacts With The Treating Physicians.

Nowhere in their Opposition do Plaintiffs explain why their counsel actually need to engage in unfettered *ex parte* contacts with treating physicians. Plaintiffs say that their counsel

need to discover evidence relevant to their failure-to-warn claims. But Plaintiffs do not explain why their counsel must discover that evidence in secret *ex parte* meetings as opposed to depositions where all parties are present. Plaintiffs also say that their counsel's *ex parte* contacts are justified because Defendants are allowed to engage in regulated contacts with the physicians as part of their routine business activities. This argument is equally unpersuasive.

**1. Plaintiffs' counsel do not need to engage in limitless *ex parte* contacts to discover evidence relevant to Plaintiffs' failure-to-warn claims.**

In issuing Pretrial Order # 48, Magistrate Judge Stanley assumed that the plaintiffs' ability to learn facts relevant to their failure-to-warn claims would be jeopardized if their counsel were required to question the physicians for the first time at deposition. *See* Defs.' Mot. at 16-17. Plaintiffs embrace this misconception throughout their Opposition.

For example, Plaintiffs rely on Magistrate Judge Stanley's statement that the "contents of corporate documents and statements of sales representatives to treating physicians and surgeons are appropriate areas of inquiry as to whether full disclosure would have changed a doctor's mind about implanting a pelvic mesh product." Pls.' Opp'n at 2, 5. Similarly, Plaintiffs insist that their counsel should have an opportunity to question the physicians about a variety of additional topics, including (1) "what they were told (or perhaps not told) about these products"; (2) "their knowledge about other product-related complications"; (3) "whether and how they were instructed and/or trained by the Defendants"; (4) "whether the frequency and severity of complications they experienced are consistent with the information they were provided by the Defendants"; (5) "the defenses in these cases relative to doctor fault"; and (6) "did you know 'x' and 'y' that Defendants knew, and would it have made any difference in how you treated this patient if you had been provided this information?" *Id.* at 5-7.

These areas of inquiry may be relevant to proving a failure-to-warn claim. But Plaintiffs' counsel can ask all of these questions at the physicians' depositions. There is *no* legitimate reason why Plaintiffs' counsel need to inquire into these areas in secret *ex parte* meetings held *before* the depositions. The only reason to do that would be to taint the physicians' memories, poison the physicians against Defendants, and "prepare" the physicians to provide testimony that is in line with Plaintiffs' litigation theories. *See* Defs.' Mot. at 8-9.

Nor do Plaintiffs' counsel need to provide the treating physicians *ex parte* with Plaintiffs' view of everything that Defendants purportedly knew about the safety of their products. Plaintiffs' counsel's obligation is not to apprise treating physicians of anything; it is to discover relevant evidence concerning the physicians' treatment decisions and to determine whether the physicians would have made different decisions had certain facts been known. As explained, Plaintiffs' counsel can satisfy that obligation—*i.e.*, they can discover "what the doctor was told – or *not* told – by the Defendants in light of the Defendants' knowledge at the time"—without providing the physicians with Plaintiffs' favored articles and documents or their spin on those materials in clandestine *ex parte* meetings. Again, the only purpose for sharing this information *ex parte* is to influence the physicians' testimony on the broader issues in this litigation. That is exactly what Plaintiffs' counsel did with Dr. Norvell in *Crews* and Dr. Woodruff in *Flowers* (*see* Defs.' Mot. at 3-5)—and apparently with hundreds of other physicians in other cases. *See* Pls.' Opp'n at 4 n.1. And it is why multiple courts have barred attorneys from engaging in these kinds of inappropriate *ex parte* contacts. *See* Defs.' Mot. at 2-6, 9-12.

In the *Actos* litigation, Judge Freeman recently considered and *rejected* the very argument that Plaintiffs make here. *See Actos Prod. Liab. Cases*, 2015 WL 1387938 at *6 ("The Court is not persuaded by Plaintiffs' argument that any limitation on counsel's ability to engage in ex

parte communications 'would severely undermine a Plaintiff's ability to prove a failure to warn claim.'"). As Judge Freeman recognized, "Plaintiffs' counsel may meet *ex parte* with treating physicians and ask them questions about the information obtained from an examination of their patients" and "may then use the information learned from the *ex parte* contacts to tailor deposition questioning." *Id.* In addition, Plaintiffs' counsel may show the physicians medical literature and company documents "during deposition . . . and ask them whether they would have made prescribing decisions had they known certain facts at the relevant time." *Id.* In short, Plaintiffs' counsel do *not* require unfettered *ex parte* access to treating physicians to discover evidence relevant to Plaintiffs' failure-to-warn claims.

Finally, Plaintiffs fail to explain how information that post-dates a physician's treatment decision—such as the select medical articles that Plaintiffs' counsel have been sharing with the physicians *ex parte*—is relevant to a failure-to-warn claim. It is not. Such information cannot prove that the physician would have made a different treatment decision at the relevant time. *See* Defs.' Mot. at 17 (citing *Hall v. Boston Scientific Corp.*, No. 2:12–cv–08186, 2015 WL 874760, at *8 (S.D. W. Va. Feb. 27, 2015)). Plaintiffs apparently concede this fact, because they fail to address Defendants' argument.

**2. Plaintiffs' counsel are not entitled to engage in limitless *ex parte* contacts with physicians just because Ethicon employees engage in regulated interactions *outside* the litigation context.**

Plaintiffs also argue that their counsel should have free reign to lobby *ex parte* in favor of their liability and causation theories because Defendants "have had contact and communication with these doctors for years." Pls.' Opp'n at 12; *see also id.* at 9 ("[T]hese Defendants have had the opportunity to provide these doctors with significant amounts of information about these products 'ex parte.'"). As part of this tit-for-tat argument, Plaintiffs insist that their counsel be allowed to share information with the treating physicians *ex parte* because Defendants

"frequently tout their products through sales calls, brochures, patient information booklets, websites, seminars and webinars." *Id.* at 12. Plaintiffs' argument has no merit.

To begin with, Plaintiffs' argument wrongly equates the conduct of lay persons *outside* of litigation with that of attorneys *in* litigation. But the context is entirely different. That Ms. Crews, for example, may interact with Dr. Norvell outside of litigation does not provide a reasonable basis for suggesting that she is seeking to influence his testimony or capable of doing so. Similarly, there is no basis for assuming that an Ethicon sales representative sought to influence a physician's testimony by providing the physician information pursuant to and consistent with regulations established by the Food and Drug Administration ("FDA"). That Ethicon interacts with treating physicians and the medical community as part of its marketing activities does not justify allowing Plaintiffs' counsel to campaign *ex parte* in favor of Plaintiffs' *litigation* theories and thereby influence the testimony of these key fact witnesses.

In addition, the premise for Plaintiffs' argument—*i.e.*, that their counsel's *ex parte* contacts are somehow necessary to correct the "pervasive . . . influence" that Ethicon supposedly has over the physicians and the medical community—lacks a factual basis. Pls.' Opp'n at 13. As the Court knows, the FDA extensively regulates the information that pharmaceutical and medical device companies may provide to treating physicians and the circumstances under which they may provide it. All distributed promotional materials must be truthful, not misleading, and consistent with the device's labeling.[2] They also are public documents. But Plaintiffs do not

[2] The FDA actively regulates labeling for all prescription medical devices as well as written materials "accompanying" the devices. *See* 21 U.S.C. § 331 (misbranding prohibited); *id.* § 352(a) (a device is misbranded if its label is "false or misleading in any particular"); *id.* § 321(m) ("'labeling' means all labels and other written, printed, or graphic matter . . . accompanying" a device). The FDA expansively interprets the term "accompanying" to include "supplementary or explanatory information disseminated by the producer of a drug or device . . . regardless of whether it physically accompanies the product." *Washington Legal Found. v.*

contend—let alone demonstrate with actual evidence—that Ethicon's marketing activities violate any FDA regulations in any respect. *See id.* at 9, 12-13. That Ethicon's sales representatives engage in lawful and regulated communications with physicians as part of Ethicon's business does not mean that Plaintiffs' *counsel* are entitled to engage in unrestrained contacts with the physicians *ex parte* as part of their *litigation* preparation efforts. Nor are Plaintiffs' counsel entitled to engage in such contacts simply because Ethicon has lawful and regulated interactions with the medical community generally.

Plaintiffs rely on Magistrate Judge Stanley's statement in the *Bard* MDL that certain internal Bard documents are "appropriate . . . for cross examination." *Id.* at 13-14. Neither Plaintiffs' argument nor Magistrate Judge Stanley's statement, however, supports the contention that Plaintiffs' counsel are therefore entitled to have those conversations *ex parte*. Cross examination is what occurs at a deposition or in court when all parties are present. When Plaintiffs' counsel meet with the physicians *ex parte*, they should not be allowed to make one-sided presentations of the evidence. Instead, the Court should limit Plaintiffs' counsel's *ex parte* contacts to a discussion of care and treatment issues.

### D. The Court Should Not Allow Plaintiffs' Counsel To Transform The Treating Physicians Into Retained Experts Before The Physicians' Fact Depositions.

The *ex parte* communications at issue here between Plaintiffs' counsel and the treating physicians are not protected by the physician-patient privilege. When a treating physician forms an opinion based on information obtained *outside* the physician-patient relationship, the physician ceases to function as a treating physician, for whom a report generally is not required,

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*Kessler*, 880 F. Supp. 26, 28 (D.D.C. 1995) (citing *Kordel v. United States*, 335 U.S. 345, 349-350 (1948)). Accordingly, under FDA regulations, a device manufacturer's promotional materials, like the labeling, must be truthful and cannot be misleading. *See, e.g.*, *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942) (printed circulars regarding drug constituted labeling).

and instead becomes a retained expert for whom a written report must be disclosed. *See* Defs.' Mot. at 12-13 (citing *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 615 (S.D. W. Va. 2013)). That is what has occurred here. By meeting with physicians *ex parte* to elicit their opinions on corporate documents and medical literature that the physicians never considered when making their treatment decisions, Plaintiffs' counsel not only irrevocably taint the physicians' fact testimony before their depositions; counsel invariably force Defendants to conduct what are in effect expert witness depositions without the benefit of the written reports that are required to prevent "trial by ambush." *Id.* at 13-14.

Plaintiffs offer no substantive response to Defendants' argument. Instead, they promise merely to comply with the Federal Rules of Civil Procedure. *See* Pls.' Opp'n at 14. Plaintiffs' promise is not enough—particularly in light of the record before the Court. Moreover, Plaintiffs' citation to this Court's opinion in the *Bard* MDL (*see id.* at 14 n.9) actually supports Defendants. In that decision, the Court acknowledged that a physician's causation opinions are admissible to the extent they were "formed in the course of treatment" of the plaintiff. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 616. Defendants should have the opportunity to elicit those opinions, as well as the physician's testimony concerning Ethicon's warnings, without the opinions and testimony having been biased by Plaintiffs' counsel's *ex parte* presentation of information that the physician did not consider at the time he or she treated the plaintiff.

## III. CONCLUSION

The Court should grant Defendants' Motion for the reasons stated. Specifically, it should limit Plaintiffs' counsel's *ex parte* contacts to a discussion of the physicians' records, course of treatment, and related matters such as diagnosis and prognosis and should bar counsel from discussing liability issues or theories, product warnings, Defendants' confidential documents, medical literature, or related materials with, or showing or providing any such documents to, the

physicians before their fact depositions. The Court also should grant Defendants any other general or special relief to which they may be entitled.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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|---|---|
| **IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL 2327** |
| **THIS DOCUMENT RELATES TO ALL CASES** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

## CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on October 6, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

*/s/ David B. Thomas*

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